

# NIXON PEABODY LLP

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## FAX

**To:**  
Boris Millis

**Company**  
USPTO PCT Legal Dept.

**Fax #** **Telephone #**  
(571) 271-0459

**RECEIVED**

**AUG 17 2010**

**PCT LEGAL  
ADMINISTRATION**

**From:**  
Mark FitzGerald

**Reply Fax #**  
(617) 345-1300

**Telephone #**  
(617) 345-1058

**Date:**  
8/17/2010 12:48:24 PM

**Pages (including cover)**  
4

**Subject:** Terminal Disclaimer for U.S. 10/560,377 (priority from PCT/US2004/019229) to accompany renewed petition under 3

### Message:

Please see attached correspondence.

Attention: Boris Millis  
USPTO PCT Legal Dept.  
Fax: 571-273-0459

From: Mark FitzGerald  
Re: Terminal Disclaimer for U.S. 10/560,377 (priority from PCT/US2004/019229) to  
accompany renewed petition under 37 C.F.R. 1.182  
Date: August 17, 2010

Dear Boris:

Per our discussion earlier today, I provide the following explanation and a draft Terminal Disclaimer for your review. I very much appreciate your help in this regard and look forward to your comments.

Best regards,

Mark

#### REMARKS

The Decision on the petition filed December 4, 2009, requesting permission to file a Continuation-in-Part (CIP) to remedy an error in the filing of U.S. 10/560,377, which should have been filed as a CIP, indicated that for the petition to be granted, and because a significant period of time has elapsed from the filing of the parent application, the Petition under 37 C.F.R. §1.182 must be accompanied by a Terminal Disclaimer disclaiming the terminal part of the term of a patent to be granted equivalent to the period between the filing date of a grantable petition under 37 C.F.R. §1.182 to convert the application to the CIP application and the filing date under 35 U.S.C. 111(a) of such application.

Applicants understand that it is inappropriate for Applicants to benefit in any way from such delay, such as extended patent term from a delay in remedying Applicants' error. As such, Applicants are certainly willing to disclaim term that would in any way extend beyond the term to which the application would have been entitled if properly filed upon U.S. National Phase entry in December, 2005. Applicants concern is that, as phrased, the Office appears to be requiring Applicants to disclaim outright all time between the effective filing date of the CIP and the filing date of the subject petition (a period of nearly 5 years), while a disclaimer of any potential benefit beyond what would have been available to the original National Phase application would have been appropriate to avoid a windfall to Applicants. Also, if no further adjustment for subsequent delay was available, then any patent issuing would have its issuance delayed by the current period AND then have a further reduction of its 20 year from filing term. However, to the extent that the disclaimer of term between the filing of a grantable petition and the June 10, 2004 filing date to be accorded the application under 35 U.S.C. 111(a) (i.e., the filing date of the parent PCT application) is a penalty, Applicants will not object, but respectfully request that the Office reconsider.

The terminal disclaimer DRAFT submitted herewith disclaims term that would extend beyond the term permissible to parent application U.S. 10/560,377 had the subject CIP been correctly filed on the date of that parent application, but subject to patent term adjustment for the CIP application under 35 U.S.C. 154 for delay occurring subsequent to the establishment of the CIP.

**TERMINAL DISCLAIMER ACCOMPANYING A RENEWED PETITION  
UNDER 37 CFR 1.182**

Docket Number (Optional)

051058-034000

In re Application of: Pachuk et al.

Application No.: New Continuation-in-Part of Application Serial No. 10/560,377, generated upon grant of the renewed petition under 37 CFR 1.182 filed herewith.

Filed: 8/17/2010

For: CONSERVED HBV AND HCV SEQUENCES USEFUL FOR GENE SILENCING

The owners\*, ALNYLAM PHARMACEUTICALS, INC., of 100 percent interest in the above-noted Continuation-in-Part application and its parent application, hereby disclaim, except as provided below, the terminal part of the statutory term of any patent granted on the subject Continuation-in-Part (CIP) application, that would extend beyond term permissible to its parent application, U.S. 10/560,377, had the subject CIP been filed on the date of that parent application. The term permitted to any patent granted on the CIP application remains subject to patent term adjustment under 35 U.S.C. 154 for delay occurring subsequent to the establishment of the subject CIP application in response to granting of the renewed petition under 37 C.F.R. 1.182 filed concurrently herewith.

This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

Check either box 1 or 2, if appropriate.

1. ☐ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record.

\_\_\_\_\_  
Signature

August 17, 2010  
Date

Mark J. FitzGerald (Reg. No. 45,928)  
Typed or printed name

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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\*Statement under 37 CF 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this statement. See MPEP § 324.